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October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually And As Guardians Ad Litem For
JASON DAUBERT, and ANITA DE YOUNG, Individually
And As Guardian Ad Litem For ERIC SCHULLER
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

**On Writ Of Certiorari To The
United States Court Of Appeals For The Ninth Circuit**

BRIEF OF AMICI CURIAE AMERICAN SOCIETY OF LAW, MEDICINE AND ETHICS DEVRA LEE DAVIS, Ph.D.; MARVIN S. LEGATOR, M.D. DONALD R. MATTISON, M.D. NATURAL RESOURCES DEFENSE COUNCIL PROGRAM ON GENDER, SCIENCE AND LAW OF COLUMBIA UNIVERSITY SCHOOL OF PUBLIC HEALTH ALLAN ROSENFIELD, M.D.; ELLEN K. SILBERGELD, Ph.D. IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

ARGUMENT 3

I. THE LOWER COURT'S PER SE RULE EXCLUDING VALID AND RELIABLE EVIDENCE VIOLATES SCIENTIFIC PRINCIPLES AND IS INCONSISTENT WITH THE PURPOSE OF THE RULES OF EVIDENCE 3

II. EXCLUSION OF EXPERIMENTAL STUDIES AND STUDIES NOT PUBLISHED IN PEER-REVIEWED JOURNALS CONTRAVENES STANDARD SCIENTIFIC PRACTICE AS EXEMPLIFIED IN FEDERAL REGULATORY PRACTICES 10

CONCLUSION 25

APPENDIX A-1

TABLE OF AUTHORITIES

CASES:

Brock v. Merrell Dow Pharmaceuticals, 874 F.2d 307, modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990) 7

Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1114, (5th Cir. 1991) 5

DeLuca v. Merrell Dow Pharmaceuticals, 911 F.2d 941 (3rd Cir. 1990) 7

Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) 1

Love v. Thomas, 858 F.2d 1347 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989) 20

Lynch v. Merrell-National Laboratories, 830 F.2d 1190 (1st Cir. 1987) 6

Natural Resources Defense Council v. Texaco Refining & Marketing, 800 F.Supp. 1 (D.Del. 1992) 4

Opp Cotton Mills v. Administrator, 312 U.S. 126 (1941) 21

Richardson v. Perales, 402 U.S. 389 (1971) 21

Richardson v. Richardson-Merrell Inc., 857 F.2d 823 (D.C. Cir. 1988), cert. denied, 493 U.S. 882 (1989) 7

STATUTES & REGULATIONS

Fed. R. Evid. 403 . . . . . passim

Fed. R. Evid. 702 . . . . . passim

Fed. R. Evid. 703 . . . . . passim

5 U.S.C. § 556(d) 21

7 U.S.C. §§ 136 . . . . . 13, 18

11 U.S.C. § 348(c)(3)(A) 13

15 U.S.C. § 2601-2629 . . . . . 13, 20

15 U.S.C. § 2079(a) 13

15 U.S.C. §§ 1261 13

29 U.S.C. § 655 14

33 U.S.C. § 1317(a) 13

42 U.S.C. §§ 300(f) 13

42 U.S.C. § 6421 14

42 U.S.C. § 6901 14

42 U.S.C. § 7412 13

16 C.F.R. § 3.43(b) 22

16 C.F.R. § 1500.17(a)(10) 13

29 C.F.R. § 1990.111(a) 14

29 C.F.R. §§ 2200.71 22

29 C.F.R. §§ 2200.72 22

40 C.F.R. § 154.7(a)(2)(i) 13

40 C.F.R. § 158.80 19

40 C.F.R. §§ 261.11(a) 14

43 C.F.R. § 4.122 22

38 Fed. Reg. 10929 14

39 Fed. Reg. 35890 14

40 Fed. Reg. 69532 13-14

41 Fed. Reg. 30476 13

42 Fed. Reg. 6532 13

43 Fed. Reg. 12308 13

43 Fed. Reg. 54353 16

44 Fed. Reg. 68624 13

49 Fed. Reg. 25734 . . . . . 12, 16

50 Fed. Reg. 10372 15

51 Fed. Reg. 23190 22

51 Fed. Reg. 33992 14

51 Fed. Reg. 33995 15

51 Fed. Reg. 34006 . . . . . 12, 16

51 Fed. Reg. 36636 20

53 Fed. Reg. 24834 12

56 Fed. Reg. 63798 11

OTHER AUTHORITIES

Administrative Conference of the United States, Resolution 86-2(1) 22

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and Toxic Risk Assessment, 5 Yale J. Reg. 89 (1988) 16

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INTEREST OF AMICI CURIAE[1/]

Amici, scientists and organizations of scientists, lawyers and others with expertise on the use of scientific information in legal proceedings, file this brief amicus curiae with the consent of the parties as provided in the Rules of this Court.[2/] We write not to express a view on the controversy over whether Bendectin causes birth defects, but because we believe that, as a general matter, scientists' ability to be of assistance to judges and juries in determining a wide range of issues is threatened by the opinions of the lower courts in this case. Those holdings, if affirmed, pose a grave danger to the incorporation of valid and reliable scientific research in determining various factual issues that arise in litigation, and as such would cripple scientists in providing a meaningful contribution to the judicial process, and courts and juries in making meaningful determinations about issues requiring scientific expertise.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Brief assumes that, for reasons recounted in the Brief for Petitioner, the rule of admissibility derived from Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), did not survive the promulgation of the Federal Rules of Evidence, and that it is those rules, standing alone, that govern the admissibility of expert scientific evidence in federal courts.

I. We begin by noting that there has been a tendency in making evidentiary rulings about expert scientific evidence first, to confuse questions of admissibility with issues pertaining to sufficiency of the evidence, and second, to seek per se evidentiary rules rather than contextual ones -- that is, principles that turn admissibility upon the purpose for which the expert evidence is sought to be introduced in the particular case, and upon the nature of the opposing evidence.

[1/] All parties have consented to the submission of this brief.

[2/] Statements of interest of each amicus appears in an Appendix to this brief.

For reasons we discuss in Part I, infra, there is a wide range of circumstance for which expert scientific evidence may be appropriate in court cases (and in those agency proceedings that apply the Federal Rules of Evidence), of which the present toxic tort causation context is only one. Any approach that regards particular kinds of evidence -- for example, animal studies, chemical analyses, or studies not published in peer reviewed journals -- as per se inadmissible with regard to human injury or harm is, as we show, likely to hamper severely the contribution of scientists to the truth-finding process that is at the heart of the judicial process.

II. In this case, the court below concluded that the methodology of plaintiff's scientists' studies was "problematic" — and therefore per se inadmissible — simply because their analyses relied upon kinds of scientific evidence other than human epidemiological studies that had been published in peer-reviewed journals.

As we show in Part II, infra, however, the methodologies used by the rejected experts (as opposed to their conclusions using those methodologies, which we do not attempt to judge) are routinely used by practicing scientists, both in the private sector and throughout government, to identify substances likely to cause human injuries. Indeed, the federal government sanctions those same methods to determine in the regulatory process the safety of food additives, drugs, cosmetics, medical devices, industrial chemicals, pesticides, and a wide range of other potentially toxic substances, and has published extensive protocols governing the conduct and interpretation of those methodologies. In those protocols, in vitro studies (laboratory studies of biochemical processes), in vivo studies (animal studies), and epidemiological studies are all expressly recognized as useful in predicting the effect of various substances on humans, and research conducted especially for the particular regulatory purpose, and not published in any peer-reviewed journal, is routinely relied upon to determine the safety of various products and processes.

It is true that the purposes and processes of regulatory agency proceedings, aimed at prospective risk elimination, differ sufficiently from retrospective jury damages trials and that the same

evidentiary standards would not apply. Nonetheless, the widespread use in regulatory proceedings of the very kinds of evidence excluded automatically here indicates scientists' reliance on those types of evidence to determine the cause of human injuries. As such, there is no basis for the per se exclusion of such evidence sanctioned by the Ninth Circuit.

ARGUMENT

I. THE LOWER COURT'S PER SE RULE EXCLUDING VALID AND RELIABLE EVIDENCE VIOLATES SCIENTIFIC PRINCIPLES AND IS INCONSISTENT WITH THE PURPOSE OF THE RULES OF EVIDENCE.

A central purpose of the Federal Rules of Evidence is to enable the fact-finder to make the most informed decision possible. The Rules accomplish this end, in part, by providing for testimony by qualified experts who possess "scientific, technical or other specialized knowledge." Fed. R. Evid. 702.

In particular, Rule 702 focusses upon whether or not expert evidence will "assist the trier of fact", which assumes that the evidence is based upon scientifically recognized and defensible methods; Rule 703 requires that the facts and data used (as opposed to the methods of evaluating that data) be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences"; and Rule 403 permits exclusion of otherwise admissible evidence, including expert evidence, where the evidence's probative value is outweighed by a "substantial danger of unfair prejudice, confusion of the issues, or misleading the jury."

(a) Rules 702 and 403 are thus "contextual" rules, turning admissibility at least in part upon the precise nature of the pertinent issues, the applicable standard of proof, and the other evidence in the case. A determination whether expert evidence will be of assistance to the trier of fact or, instead, is more likely to mislead the jury thus depends on the purpose for which it is being offered -- for example, whether the evidence is being introduced to prove

causation in a products liability case, or, instead, to help establish a different cause of action, with different elements.

Thus, in a constitutional libel case, parties may seek to introduce scientific evidence supporting the truth of a published assertion to demonstrate absence of "malice" or lack of reckless disregard for the truth. The truth or falsity of the scientific assertion in such a case may be less important than whether the party's reliance on it was reasonable.

Similarly, the parties in an age discrimination case may introduce expert scientific evidence regarding the validity of an employer's medical policy or benefit plan, in an effort to prove discriminatory intent. And parties bringing "citizen suits" in the federal courts to obtain injunctive relief for alleged violations of the federal Clean Water Act, Clean Air Act, the National Environmental Policy Act and similar statutes rely on scientific evidence from the frontiers of science to prove that an enterprise threatens human health or the environment. Davis, The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review, 10 Colum. J. Envtl. L. 67 (1985); J. Bonine & T. McGarrity, The Law of Environmental Protection, pp. 797-815, 861-866 (2d ed. 1991), and see, e.g., Natural Resources Defense Council v. Texaco Refining & Marketing, 800 F.Supp. 1, 7, n.2 (D.Del. 1992). Where the question is whether someone reasonably believed something to be true, or whether an impermissible motive precipitated certain acts, or whether there is a risk of harm from a particular chemical exposure, the range of relevant, admissible scientific evidence might, under Rules 702 and 403, be broader than where the issue is one of actual causation related to a particular individual's injury.

Similarly, some kinds evidence could be helpful, and not unduly prejudicial, when there is no other kind of evidence available because of the practicalities of certain kinds of scientific research, see Part II, infra, but it would not be helpful and might be misleading where more direct evidence is readily available but has not been produced.

(b) Rule 702, however, also arguably involves a per se element, insofar as it is read to incorporate into the "assist the trier

of fact" standard some judicial ability to assure use of responsible scientific methodology. And Rule 703 suspends the hearsay rule on an objective, per se basis, unrelated to the issues, standard of proof, or opposing evidence in the particular case.[3]

There is no basis in the language of either Rule 702 or Rule 703, however, for erecting a per se standard of admissibility stricter than the standard used by scientists themselves in determining whether a study sufficiently partakes of the attributes of scientific research to be regarded as probative by scientists in the relevant field. And, to working scientists, the credibility or value of a scientific approach or opinion depends more on the strength of the factual premises, on the compatibility with other known facts, and on the methodology and reasoning, than the number of scientists who agree with the result or the fact that the contrary opinion can also be supported by reference to respectable scientific research.

To comport with this fundamental aspect of the scientific process, the evidentiary rules must be interpreted flexibly enough to permit the introduction of scientific opinions and evidence from qualified experts based on what they reasonably believe is valid and reliable. The decision on whether or not to submit a particular study or data to peer review for publication often turns on factors entirely unrelated to the scientific validity or value of the evidence at issue. And expert opinions may address areas in which little direct empirical research has been done because of the novelty of the problem; or may represent a respectable but minority view among scientists; or may be based on the use of established

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[3] There is a debate in the case law, which we do not address, concerning whether or not Rule 703 applies the "reasonably relied upon by experts in the particular field" standard only to the raw data relied upon, or also to the interpretation of that data. See, e.g., Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1114, 1118-20 (5th Cir. 1991); (Clark, J., concurring in the result), cert. denied, ___ U.S. ___, 112 S.Ct 1280 (1992). For present purposes, it suffices to note that there is some objective, non-contextual review appropriate under Rule 703, at least insofar as expert testimony relies on hearsay.

methodologies upon data collected or aggregated in innovative ways; or may constitute critiques of the existing body of research on bases appropriate in reviewing scientific studies.

In any of these circumstances, per se exclusion of the informed opinions of qualified scientific experts, for example because the underlying studies relied upon have important limitations or are not published in peer-reviewed scientific journals, would leave the judicial process the poorer. Such automatic exclusion, instead, should be reserved for circumstances in which the basic methodology (not the ultimate conclusions) of the research relied upon is simply outside the realm of scientific respectability.

We are not suggesting that the opinion evidence of plaintiffs' experts in this case properly could or should have been excluded even under the contextual standards for expert testimony, as insufficiently helpful concerning the causation issue, or as too misleading given its probative value. Rather, our point is more general: There may be circumstances in which scientific evidence could be excluded on these bases, taking into account the elements of the cause of action, the opposing expert evidence, and the practical reasons why the particular type of scientific evidence is being offered as opposed to some other type. And since such contextual weighing is available under the Federal Rules, it is to be preferred over a more automatic approach, which will only lead to mandatory ignorance in the courtroom, and poorer judge and jury decisionmaking in a wide variety of circumstances.

(c) The history of Bendectin litigation in various courts illustrates another reason why automatic exclusion of scientific evidence should be confined to extreme situations of breach of basic standards of scientific method: While some courts, like the Ninth Circuit in this case, have excluded entirely from evidence any expert testimony based upon non-epidemiological studies and studies not published in peer-reviewed journals, other appellate courts have precluded judgment for plaintiffs on the basis that those same kinds of evidence, while admissible, are insufficient to sustain a verdict for the plaintiff. Compare Lynch v. Merrell-National Laboratories, 830 F.2d 1190 (1st Cir. 1987); Richardson v. Richardson-Merrell Inc., 857 F.2d 823 (D.C. Cir. 1988), cert. denied, 493 U.S. 882

(1989) with Brock v. Merrell Dow Pharmaceuticals, 874 F.2d 307, modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990). As the Third Circuit noted in DeLuca v. Merrell Dow Pharmaceuticals, 911 F.2d 941, 958-59 (3rd Cir. 1990), the conclusion that in some circumstances a case may be appropriate for summary judgment, or for a directed verdict, even though there is some admissible expert evidence supporting plaintiff's theory of causation, relates to the applicable burden of persuasion: Even if disputed expert testimony is admissible, that testimony "may be found sufficiently helpful to support a jury finding that Bendectin can cause birth defects or even that Bendectin not infrequently causes birth defects", but still would not bar summary judgment for defendants "unless it would support a jury finding that Bendectin more likely than not caused the birth defects in this particular case."[4] In other words, the expert evidence may be sufficient to prove some increased risk of a particular harm due to exposure to a particular substance, but not to exclude as more probable the conclusion that other causes are responsible.[5]

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[4] We note that, as the DeLuca court stated, sufficiency of the evidence would, in a toxic tort case such as this one, necessarily be tested against the burden of proof standard under applicable state law. 911 F.2d at 958-59.

[5] For example, the expert evidence might show that it is ten percent more likely that a person exposed to a particular substance will get cancer than one who is not so exposed, while indicating at the same time that ninety percent of the people who get the same form of cancer have no such exposure, and must have gotten the cancer from some other, unknown source. Under those circumstances, it is arguable whether summary judgment might be appropriate in a toxic tort context because there is no evidence indicating that it is more probable that the particular case of cancer in question was caused by the putative exposure than by one of the unknown causes.

We note that the very same expert evidence would, however, almost surely support a regulatory or judicial finding that the substance in question presents an unreasonable risk to human

(continued...)

We take no position on the propriety of summary judgment or a directed verdict on this record or on the record in any of the other Bendectin cases. What conclusion might be reached if the courts below had considered all the valid and reliable research that has been conducted on Bendectin is impossible to predict. Admitting such testimony and evidence does not signify that it will be sufficient to meet the requisite burden of proof (or, if it is sufficient on its face to survive a motion for summary judgment, that plaintiff's experts rather than defendants will be credited by the jury after the rigors of cross-examination). Even if those hurdles are met, the plaintiff must still provide evidence sufficient to survive summary judgment on the additional elements of the cause of action in order to advance to trial.

The summary judgment approach, however, where proper on the evidence presented, is considerably more respectful of the uneasy interaction of science and law than total exclusion of expert testimony. By admitting the evidence and then testing it against the applicable burden of persuasion, courts can adjust directly for the differences between scientific and legal decision-making, rather than hiding that decision behind an evidentiary ruling. In doing so, courts can allow cases to go forward depending upon the precise elements of plaintiffs' cause of action and burden of proof, and a detailed consideration of plaintiffs' total evidence on the point for which expert evidence is introduced, rather than on each piece of evidence in isolation.

(d) Both the court of appeals and the trial court in this case, however, misinterpreted their proper role in ruling on the

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[9](...continued)
health and should be prospectively excluded from the market under a statute providing for exclusion on that standard. See also Part II, infra. The reason for the different results is that the substantive inquiries are fundamentally different where the question is causation of an individual injury, as opposed to assessment of the risk posed to the population as a whole. Any per se evidentiary approach, in contrast, would treat the two situations as equivalent, and exclude the expert evidence entirely in a court case in both circumstances.

admissibility of evidence. The trial court searched for a consensus in the scientific community by looking at how other courts disposed of similar claims on the merits. It thus discerned and relied on a "consensus" in the legal community, not the scientific community, on the ultimate question to be determined -- whether there is sufficient evidence of a causal link between Bendectin and certain birth defects to support a judgment for the plaintiffs, a process that merged evidentiary questions with the determination on the merits. This error was compounded by the fact that some of the courts included in this "consensus" had themselves excluded types of evidence that scientists normally rely on, especially animal and other experimental data, a determination the trial court specifically endorsed in holding that causation could only be demonstrated through epidemiological data.

The appellate court, similarly, sought to limit the admissibility of evidence to facts and opinions apparently consistent with the "consensus" on the merits of the causation issue in the case. By doing so, the Ninth Circuit likewise failed to separate evidentiary determinations from scientific methodology considerations, and methodological considerations from the conclusions that are drawn from the application of a particular methodology to properly collected data. Thus, the courts below both apparently sought to preclude litigation they viewed as repetitive on the ultimate causation questions by use of inappropriately restrictive evidentiary rulings.

What is clear, however, is that a scientific consensus exists that in order to determine the ultimate questions of risk and causation, all methodologically valid and reliable sources of data and analysis of data must be evaluated. This the courts below failed to do. The exclusion of scientifically relevant information from consideration violates both legal and scientific norms and, unless corrected by this Court, will predictably distort the legal fact-finding process.

II. EXCLUSION OF EXPERIMENTAL STUDIES AND STUDIES NOT PUBLISHED IN PEER-REVIEWED JOURNALS CONTRAVENES STANDARD SCIENTIFIC PRACTICE AS EXEMPLIFIED IN FEDERAL REGULATORY PRACTICES.

Instead of permitting an evaluation of valid and reliable data from the sources that scientists normally use, the courts below, and other courts they cite, irrationally and artificially limited the universe of relevant facts. Those courts concluded that the apparently negative epidemiological data could not be rebutted by experimental data, and that only positive epidemiological studies published in peer-reviewed journals could suffice to prove causation.

The question then becomes whether scientific opinion concerning causation of human harm is, as a general matter, outside the realm of scientific respectability unless based on human epidemiological studies published in peer-reviewed journals. Otherwise, the decision below was incorrect, and should be reversed. One need look no further than the practices of numerous federal agencies staffed by experienced and respected scientists to discover that the courts below were simply wrong in so narrowly restricting the realm of scientific information useful in coming to an informed conclusion on a causation issue such as the one in this case.

(a) A rule in cases involving toxic substances limiting admissibility to peer-reviewed human epidemiological studies misapprehends, first, the nature of scientific inquiry into causation, and the nature and limitations of epidemiology. Data from well-designed and well-conducted human epidemiology may be a highly desirable form of data, but many factors preclude that methodology from being the sole or principal authority upon which courts should rely in determining causation of human harm generally, or in assessing reproductive and developmental risk particularly. And although experimental data have drawbacks that may sometimes limit their usefulness in assessing human risk and causation issues, similar methodological difficulties apply to epidemiology as well. These considerations, however, do not preclude scientists from

making valid conclusions about causation in appropriate circumstances.

(1) First, as evidenced in virtually all federal regulations dealing with toxic risk assessments, experimental data based on studies of animals are a critical element of the process of assessing the nature and extent of health risk associated with chemical and other exposures and in evaluating the causal relationship between such exposures and certain adverse outcomes, including but not limited to birth defects and other developmental and reproductive effects.

For example, the Environmental Protection Agency ("EPA"), the federal agency charged with enforcement of the nation's most comprehensive public safety and health statutes, and with the overall regulation of toxic substances, recently issued Final Guidelines for Developmental Toxicity Risk Assessment ("Guidelines"), 56 Fed. Reg. 63798 (1991). The Guidelines resulted from extended regulatory proceedings in which both agency scientists and members of the relevant scientific community participate, and were issued after public notice and an opportunity to comment. As such, they represent a close approximation of a "consensus" approach to an inquiry into appropriate research methods for discovering the cause of adverse developmental outcomes.

The Guidelines restate a fundamental scientific premise, ignored in the evidentiary rulings in this case:

> Hazard identification/dose-response evaluation involves examining all available experimental animal and human data and the associated doses, routes, timing and duration of exposures to determine if an agent causes developmental toxicity....

Id. at 63799 (emphasis added). Moreover, the significance of animal data in assessing human reproductive risk is specifically noted:

> [I]t is assumed that an agent that produces an adverse developmental effect in experimental animal studies will potentially pose a hazard to humans following sufficient exposure during development ... . [I]n almost all cases, experimental animal data are predictive of a developmental effect in humans.

Id. at 63801.

Similarly, in the detection of agents capable of altering genetic material in sperm or ova (mutagens), creating a risk of heritable or transmissible injury to future generations after exposure of either parent, EPA has determined that it is "appropriate to rely on data from experimental animal systems...."[9] See also Environmental Protection Agency, Proposed Guidelines for Assessing Female Reproductive Risk, 53 Fed. Reg. 24834, 24836 (1988) (reiterating the need for reliance on "evaluation of toxicological data from humans and experimental animals..." in making reproductive and developmental risk assessments)(emphasis added); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25734, 25743-4 (1984)(describing the agency's "comprehensive review of the scientific evidence... from many investigations in several species of experimental animals ...as well as positive results from several human studies," and noting that a rat study "provided the strongest evidence" of the carcinogenic properties of EtO.).

The significance of experimental data is further acknowledged by the multi-billion dollar research investment funded over the last 40 years by the National Institutes of Health. The majority of that funding has gone to support bio-medical research using experimental models. See, e.g., T.J. Gill, et al., The Rat As An Experimental Animal, 245 Science 269 (1989). Nobel Prizes in physiology and medicine have frequently been awarded for research using experimental animals. See 8 Encyclopedia Britannica 740-47

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[9] Environmental Protection Agency, Guidelines for Mutagenicity Risk Assessment, 51 Fed.Reg. 34006, 34008 (1986).

(1991). Our understanding of genetics and molecular biology began with research on fruit flies and worms in the 1920s, and this research formed the basis for the identification of major human diseases. J.D. Watson, et al., Molecular Biology of the Gene (4th ed. 1987). These sources only begin to suggest the fundamental nature that experimental data play in shaping scientific knowledge and opinion. See also National Academy of Sciences, National Research Council, Biological Markers in Reproductive Toxicology (1989); National Academy of Sciences, Principles for Evaluating Chemicals in the Environment (1975).[7]

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[7] A partial list of federal laws, regulations and standards in which animal studies are used to assess human health risks includes: the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-137, and accompanying regulations, e.g., 40 C.F.R. § 154.7(a)(2)(i); Federal Food, Drug and Cosmetic Act, 11 U.S.C. § 348(c)(3)(A) ("no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"); the Consumer Product Safety Act, 15 U.S.C. § 2079(a) and the Federal Hazardous Substances Act § 2(f)(1)(A), 15 U.S.C. §§ 1261, 1262, and accompanying regulations, e.g., 16 C.F.R. § 1500.17(a)(10), and 43 Fed. Reg. 12308-12310 (animal studies are the basis for classification as banned hazardous substances of self-pressurized household substances containing vinyl chloride monomer); Safe Drinking Water Act, 42 U.S.C. §§ 300(f), et seq., and accompanying regulations, e.g., 44 Fed. Reg. 68624, 27; Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1976), especially §2603(b)(2)(A) (providing for "standards for the development of test data", including "epidemiological studies, serial or hierarchical test, in vitro tests, and whole animal tests," emphasis supplied); Federal Water Pollution Control Act, § 307(a), 33 U.S.C. § 1317(a) (1976), and accompanying regulations, e.g., 41 Fed. Reg. 30476-77 (1976) and 42 Fed. Reg. 6532 (1977) (proposed and final discarges standards for PCBs based on evidence of animal carcinogenicity); Federal Clean Air Act, 42 U.S.C. § 7412, and accompanying regulations, e.g., National Emission Standards for Hazardous Air Pollutants: Proposed Standard for Vinyl Chloride, 40 Fed. Reg. 69532 (December 24, 1975) (rationale for the standard includes

(continued...)

Thus, there are both clear standards for "good" experimental science and accepted principles governing the applicability of such data to humans.

(2) The basis for consensus as to the importance of experimental data is not only that such data are crucial to an understanding of the mechanisms of causation of human injury, but also that human epidemiology is for various reasons intrinsically limited in this respect. Together the two forms of investigation provide complementary information that can lead to a much fuller understanding of risk and causation than either, separately, permits.

First, "[e]pidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk....Negative results cannot prove the absence of [risk]...." EPA Final Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992, 33995-96 (1986).

Thus, positive epidemiological study establishes a statistical probability that a particular agent causes a particular effect. And, of greater import in this case, because of the heavy reliance placed by the lower courts on the negative epidemiological data, is the fact

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animal test data demonstrating carcinogenicity of vinyl chloride as well as epidemiological studies); Occupational Safety and Health Act, 29 U.S.C. § 655, and standards issued thereunder, e.g., OSHA Cancer Policy, 29 C.F.R. § 1990.111(a), relying on positive results in high-dosage animal tests "to establish the qualitative inference of carcinogenic hazard to workers", and 39 Fed. Reg. 35890, 35891 (1974), 38 Fed. Reg. 10929 (1973) (OSHA exposure standards for vinyl chloride and ethyleneimine, respectively, based on animal studies indicative of carcinogenicity); and the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq., especially 42 U.S.C. § 6421 and implementing regulations at 40 C.F.R. § 261.11(a) (including as a hazardous waste substances that "have been shown in scientific studies to have toxic, carcinogenic, mutgenic or teratogenic effects on humans or other life forms." (emphasis supplied)).

that the absence of a statistically significant relationship in a particular study does not necessarily signify the absence of a cause and effect relationship:

> A high-quality negative epidemiological study, while useful, cannot prove the absence of an association....

Office of Science and Technology Policy, Chemical Carcinogens: A Review of the Science and its Associated Principles, 50 Fed. Reg. 10372, 10378 (1985); see also EPA Final Guidelines for Carcinogen Risk Assessment, supra, 51 Fed. Reg. 33995 (human epidemiology "can rarely be used to make a causal inference").

The failure to discover a statistically significant relationship between a particular exposure and effect may occur because the effect does not exist, or it may occur because the study has too few subjects, failed to control for confounding variables, or for other reasons. Experimental studies demonstrating a biologically plausible mechanism by which injury could occur and the existence of such an effect in other species or test systems are an essential aspect of the inquiry into causation, because they can explain what has been observed through epidemiological inquiries. See E.K. Silbergeld, The Role of Toxicology in Causation: A Scientific Perspective, 1 Courts, Health Science & the Law 374, 381 (1991) ("[n]otions of cause in science involve knowledge of mechanism. They go beyond the accumulation of linked observations...."); see also A.S. Evans, Causation & Disease, 49 Yale J. Biol. & Med. 175 (1976).

Retrospective studies relying on individuals' accounts or on medical records that may be incomplete or inaccurate may be unreliable. Because epidemiology confirms past harms, experimental methods which seek to predict and avoid such harms have obvious advantages. D.L. Davis, Changing Policy Rules of Environmental Epidemiology, 3 Statistical Science 281 (1988).

Furthermore, as a practical matter,

> [r]eliable epidemiologic data on long-term human risks cannot exist for recently introduced toxic

> substances and is rarely available for chemicals in longstanding use. Thus, most attempts to regulate toxic hazards must rely on extrapolation of human risks from animal test data.

Latin, Good Science, Bad Regulation, and Toxic Risk Assessment, 5 Yale J. Reg. 89, 103 (1988).

One reason that it is difficult to obtain epidemiologic data is that for such studies large populations need to be studied over an extensive time period; cancer may take decades to develop, while some heritable disorders may only be observable after two or more generations. Reliance on experimental data avoids some of these problems and, in addition, is justified because "chemicals causing genetic effects in one species or test system frequently cause similar effects in other species or systems." 51 Fed. Reg. 34008.

In short, all forms of scientific data are subject to criticism on one methodological ground or other,[#] but that does not preclude valid judgments and determinations regarding causation if the various approaches are used with an understanding of their power and their limitations. The response of regulatory agencies has been consistent in their reliance on all sources of information where data have been generated through accepted scientific methodology and according to good scientific practice. By directly and indirectly excluding information that regulatory agencies and

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[#] The limitations of epidemiology are apparent from the foregoing discussion. Indeed, if plaintiffs here had relied on epidemiological data, there is little doubt that the defendants would have challenged that data as insufficient methodologically. The history of regulatory proceedings assessing the risks of toxic exposures demonstrates that questions have been raised about the validity and pertinence of data of all sorts, including published, peer-reviewed, epidemiological data. See, e.g., Attachments to the Preamble for the Final Standard for Occupational Exposure to Lead, 43 Fed. Reg. 54353 - 54509 (1978); Occupational Safety and Health Administration, Final Standard for Occupational Exposure to Ethylene Oxide, 49 Fed. Reg. 25734, 25739 (1984).

most practicing scientists deem essential in determining risk and causation issues, the courts below have adopted an indefensible view of what counts in scientific inquiry.

(b) Similarly, by excluding all scientific evidence not published in peer-reviewed journals, the courts below barred from legal consideration a wide range of scientific material upon which scientists as well as policy makers routinely rely. Indeed, a massive amount of valid and rigorous scientific data is not published in peer-reviewed journals, and would be excluded under the standard applied below.

The best illustration that scientific evidence can be reasonably relied upon by experts in the field, even if it has not appeared in a peer-reviewed journal, can be seen in the working of the federal agency created to test the safety of chemicals. The National Toxicology Program (NTP) was established in 1978 by the Secretary of the then Department of Health, Education and Welfare to test chemicals for their health effects and to develop and validate improved test methods. NTP routinely conducts experimental studies to determine whether substances are carcinogenic or have other adverse health effects. The results of these studies are issued directly by NTP in the form of a Technical Report.

As of July 1992, NTP had issued four hundred sixteen Long Term Technical Reports and Short Term Toxicity Study Reports for hundreds of chemicals. These Technical Reports are widely relied upon by state and federal agencies for a host of decisions on regulating toxic substances, resolving disputes between conflicting studies, and similar purposes[#].

It would be inappropriate for two reasons to publish the results of an NTP cancer study in a peer-reviewed journal.

[#] NTP employs an external scientific review process to insure the integrity of its research, but results are not published in a peer-reviewed journal and would not meet the per se standard adopted by the Ninth Circuit in this case.

First, if the NTP determines that a substance is carcinogenic, withholding the release of the study results pending acceptance in a peer-reviewed journal would delay the initiation of the appropriate regulatory process to consider how to protect the public. In fact, NTP anticipated this kind of situation and established a procedure whereby, if preliminary evidence suggests that a chemical is highly carcinogenic, federal regulatory agencies, manufacturers, trade associations, labor unions, public interest groups, and others are affirmatively notified even before the Technical Report is completed. To await the completion of a journal's peer review process could unnecessarily prolong the public's exposure to a harmful substance.

Second, the vast majority of the studies used to evaluate the health effects of chemicals are conducted using widely accepted and very explicit scientific protocols. Because these protocols have become so commonplace, the studies are not likely material for journals that necessarily must seek research on new scientific methods. This absence of peer review, however, has no bearing whatsoever on the scientific quality or probative value of NTP Technical Reports or their acceptance in the scientific community.

Moreover, data not published in peer-reviewed journals are commonly used for many other varieties of scientific and regulatory purposes. Under a broad array of federal statutes, including the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), The Federal Food, Drug and Cosmetic Act (FFDCA), the Toxic Substances Control Act (TSCA), and others, manufacturers are required to test their compounds for health and environmental effects as a condition for receiving government approval for sale and use. Generally, these studies, conducted in accordance with standardized test procedures in order to ensure their validity, are submitted to the appropriate federal government to determine how the compounds should be regulated.

For example, FIFRA requires that all pesticides sold or distributed in the United States must be registered by the U.S. Environmental Protection Agency. FIFRA § 3(a), 7 U.S.C. § 136(a). Such data are used to determine whether the statutory standard for registration has been met, i.e., that a pesticide "when

used in accordance with widespread and commonly recognized practice ... will not generally cause unreasonable adverse effects on the environment." FIFRA § 3(c)(50(D), 7 U.S.C., § 136a(c)(5)(D).

EPA publishes detailed guidelines specifying the type of data necessary to support a pesticide registration. FIFRA § 3(c)(2), 7 U.S.C. § 136a(C)(2). The regulatory guidelines, and the underlying Pesticide Assessment Guidelines and Standard Laboratory Practices, explicate requirements for over a hundred different studies on the health and environmental effects of individual pesticides. Yet nowhere in the federal statute or the regulatory guidelines is it required that a study be published in a peer-reviewed journal as a precondition for consideration in EPA's pesticide registration decision. Rather, in its general policy regarding acceptability of data, the Agency will:

> determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible.

40 C.F.R. § 158.80 (1988).

To date, over six hundred pesticide active ingredients have been federally registered for use, largely on the basis of studies not published in peer-reviewed journals.[19]

Analogously, pursuant to Section 8(e) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e), manufacturers must immediately disclose to EPA any adverse effects caused by their products. On September 15, 1992, for example, by letter IBM Corporation notified EPA under TSCA Section 8(e) that diethylene glycol dimethyl ether and ethylene glycol monoethyl ether acetate caused adverse reproductive effects, including increased spontaneous abortions. This disclosure was based on a preliminary, and yet unpublished, analysis of 1980-1989 data collected as part of an epidemiological study of IBM's semiconductor manufacturing employees and their work environment at two sites.

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[19] Similarly, Section 6 of FIFRA authorizes the Administrator to cancel or suspend pesticide registration if the product does not comply with FIFRA or generally causes unreasonable adverse effects on the environment. FIFRA § 6, 7 U.S.C. § 136d. The Administrator's cancellation or suspension decision is not limited to consideration of studies published in peer-reviewed journals. In fact, the statute requires pesticide registrants at any time to submit to EPA "additional factual information" regarding a pesticide's unreasonable adverse effects, a category clearly far broader than only information published in a peer-reviewed journal.

EPA routinely cancels or suspends pesticides on the basis of studies not published in peer-reviewed journals. For example, on October 7, 1986, EPA issued an emergency suspension of a widely used pesticide ingredient, dinoseb. The suspension order was based upon scientific data EPA summarized as demonstrating that "dinoseb is a developmental toxicant in laboratory animals." 51 Fed. Reg. 36636 (October 14, 1986). These data were unpublished studies submitted to EPA by dinoseb's manufacturers but deemed by the Agency to be scientifically valid and sufficient indicators of cause for concern to warrant suspension of the pesticide. See Love v. Thomas, 858 F.2d 1347 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989).

(c) None of this is to say that the same ultimate evidentiary considerations apply in agency regulatory proceedings as in judicial jury trials concerning individual causation. Indeed, the Federal Rules of Evidence, as such, ordinarily do not apply in regulatory risk-assessment proceedings.

The Administrative Procedure Act provides that technical rules for the exclusion of evidence do not apply before federal agencies. Under the APA, "any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556(d).

Specific statutes, however, can override the application of the APA to agency hearings. In addition, agencies can voluntarily adopt their own evidentiary rules.

Upon enacting the APA, Congress codified case law establishing that exclusionary rules were inapplicable to agency proceedings. This Court stated in 1941 that "it has long been settled that the technical rules for the exclusion of evidence applicable in jury trials do not apply to proceedings before federal administrative agencies in the absence of a statutory requirement that such rules are to be observed." Opp Cotton Mills v. Administrator, 312 U.S. 126, 155 (1941).

In 1971, in Richardson v. Perales, 402 U.S. 389 (1971) the Court indicated that it favored a broad interpretation of agency authority to admit and rely on reliable hearsay. Richardson held that physician reports adduced by the agency were admissible and satisfied the requirement of "substantial evidence" though opposed by live expert testimony on behalf of claimant.

Enactment of the Federal Evidence Rules in 1975, however, brought about a perceptible change in attitude in Congress and in several of the administrative agencies themselves. McCormick, Evidence § 351. No longer was it assumed that formal evidentiary rules would not apply in any given administrative agency hearing.

Presently, four types of agency rules exist: (1) Rules following the wide open standard of the APA, see, e.g., 16 C.F.R. § 3.43(b) (FTC); 43 C.F.R. § 4.122 (Interior), (2) Rules that permit use of the FRE as a source of guidance, (3) Rules requiring that presiding officers apply the Federal Rules of Evidence "so far as practicable," and (4) Rules adopting the Federal Rules of Evidence without qualification, see 29 C.F.R. § 2200.72 (OSHA).

As of the mid-1980s, of 280 evidentiary regulations, 37 made reference to the Federal Rules of Evidence, most requiring their use "as far as practicable." McCormick, Evidence § 351; citing Pierce, Use of the Federal Rules of Evidence in Federal Agency Adjudications, 39 Admin. L. Rev. 1, 6 (1987). Only the Occupational Safety and Health Review Commission has adopted the Federal Rules of Evidence without qualification. See 29 C.F.R. § 2200.71.[11/]

Alarmed by the increasing application of the Federal Rules of Evidence in administrative hearings, the Administrative Conference of the United States on June 20, 1986, adopted Resolution 86-2(1). According to Kenneth Davis, this recommendation "now overshadows all other law about evidence in administrative proceedings," and "is about as effective as a statute

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11/ Prior to implementing the present rule, OSHRC allowed use of the Federal Rules of Evidence "insofar as practicable." In proposing the present rule, OSHRC stated that the "insofar as practicable" standard created "uncertainty," and that "it is difficult to imagine a situation in which it would not be 'practicable' to follow the Federal Rules of Evidence." 51 Fed.Reg. 23190 (June 25, 1986). OSHRC stated that "[i]n practice, the Commission expects that the revision of its rule on the admissibility of evidence would have only a limited effect on Commission proceedings...Even as to hearsay, where the Federal Rules were previously not followed strictly, the change to a strict application of the hearsay rules probably will not result in a significantly different resolution of factual issues. Often, evidence admitted under the Commission's lenient policy towards hearsay also would have been admissible under the Federal Rules."

to the same effect would be." Davis, Administrative Law of the Eighties, 1989 Supplement to Administrative Law Treatise 382. Resolution 82-6 provides:

> Congress should not require agencies to apply the Federal Rules of Evidence, with or without the qualification "so far as practicable," to limit the discretion of presiding officers to admit evidence in formal adjudications.
>
> Agencies should adopt evidentiary regulations applicable to formal adversarial adjudications that clearly confer on presiding officers discretion to exclude unreliable evidence and to use the weighted balancing test in Rule 403 of the Federal Rules of Evidence, which allows exclusion of evidence the probative value of which is substantially outweighed by other factors, including its potential undue consumption of time.
>
> To facilitate the efficient and fair management of the proceeding, when otherwise appropriate, an agency should announce in advance of a formal adjudication as many of the factual issues as the agency can foresee to be material to the resolution of the adjudication.

As we have seen, regulatory proceedings also apply statutory substantive standards that are often immeasurably more risk-adverse than the "more likely than not" causation standard of civil litigation, since the aim is prospective prevention of harm rather than retrospective assignment of responsibility for loss. See n. 5, supra. Moreover, federal regulatory statutes ordinarily (but not always; see p. 4, supra) entrust the ultimate determination to expert decisionmakers with the background to give due weight to scientific evidence that lay juries may not have.

These differences between jury trials and agency regulatory proceedings may well support the exclusion of some scientifically relevant evidence, used by federal agencies in making risk

assessment decision, under the contextual approach of Fed. R. Evid. 403, for tendency to confuse or prejudice the jury. Those differences may also permit the grant of summary judgment to defendants where an agency would conclude that the risk is unreasonable and should be abated, because of the difference in the applicable substantive standard in civil litigation. The practice and judgment regarding the difficulty of extrapolating conclusions about human risk factors from available scientific methodologies, and the need therefore to consider a broad range of evidence in drawing such conclusions, is nonetheless of paramount importance in condemning the contrary, per se exclusionary approach of the courts below.

CONCLUSION

For the reasons stated above, the judgment of the Ninth Circuit should be reversed.

Respectfully submitted,

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APPENDIX

STATEMENT OF INTEREST OF AMICI CURIAE

The American Society of Law, Medicine and Ethics was founded in 1972 to provide a forum for interdisciplinary discussion of the complex issues at the interface of law, medicine, ethics and health. Ongoing informational efforts include the publication of two quarterly journals, Law Medicine and Health Care, a leading forum for interprofessional analysis of current issues, and the American Journal of Law, Medicine and Ethics, a law review co-published with the Boston University School of Law. For the reasons stated in the attached brief, the Society believes that all valid and reliable scientific research, conducted according to professional standards, should be admissible in legal proceedings.

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Marvin S. Legator, M.D., is Director of Environmental Toxicology, Department of Preventive Medicine and Community Health, University of Texas Medical Branch. He served for ten years as Chief, Genetic Toxicity Branch of the FDA, and was Chairman of the March of Dimes Committee on Reproductive Hazards. Dr. Legator has published extensively in the areas of genetics and toxicology.

Donald R. Mattison, M.D., is Dean of the Graduate School of Public Health and Professor of Environmental and Occupational Health and Obstetrics and Gynecology at the University of Pittsburgh. From 1978 to 1984, Dr. Mattison was director of the reproductive toxicology program in the Pregnancy Research Branch, National Institute of Child Health and Human Development, National Institutes of Health. From 1984 to 1990, he was Professor of Obstetrics and Gynecology and Toxicology at the University of Arkansas for Medical Sciences. During this period he also served as acting director of the human risk assessment program at the National Center for Toxicological Research, a component of the Food and Drug Administration. Dr. Mattison has published widely in the area of reproductive toxicology, and, among other activities, was editor of a volume entitled Reproductive Toxicology, published by the American Journal of Industrial Medicine (vol. 4, Number 1/2, 1983).

The National Resources Defense Council (NRDC), a nonprofit corporation whose principal place of business is at 122 East 42nd Street, New York, NY, has offices in Washington, D.C. and San Francisco, CA, and a membership of more than 175,000 persons from across the United States and in several other nations. NRDC is dedicated to the preservation, enhancement and defense of the human environment and natural resources of the United States. In carrying out these objectives, NRDC has undertaken efforts both before government regulatory bodies and the courts to obtain clean air, clean water and toxic substances control, including activities to ensure effective implementation of health and environmental protection statutes. In connection with these activities, NRDC has on numerous occasions relied upon and supported governmental reliance upon both laboratory animal and epidemiological animal studies to assess the risks that exposure to chemicals poses to humans, including studies that have and have not been formally peer-reviewed.

The Program on Gender, Science and Law at the Columbia University School of Public Health is a multidisciplinary program composed of scientists, lawyers, and scholars who are

dedicated to exploring mixed issues of science, law and public policy, particularly in areas that affect women's health and well-being. Faculty members associated with the Program have substantial expertise applying scientific knowledge to resolution of legal disputes, have made scholarly study of these issues, and have dealt with them on a practical level as attorneys and expert witnesses.

Allen Rosenfield, M.D., is Dean of the School of Public Health at Columbia University, DeLamar Professor of Public Health, and Professor of Obstetrics and Gynecology. Before assuming this position, Dr. Rosenfield had a distinguished career in family planning and maternal and child health, both nationally and internationally. Dr. Rosenfield is a diplomate of the American Board of Obstetrics and Gynecology, a fellow of the American College of Obstetrics and Gynecology, and a Member of the Institute of Medicine. He serves on numerous boards and committees, acts as advisor to governmental agencies and other organizations, and has published more than 85 scientific articles.

Ellen K. Silbergeld, Ph.D., is Professor of Epidemiology at the University of Maryland School of Medicine. Prior to this, she was Chief of the Section on Neurotoxicology, National Institute of Neurological Diseases and Stroke at the National Institutes of Health, Guest Scientist in the Reproductive Toxicology Section, Pregnancy Research Branch at NIH, and Chief Toxics Scientist and Director of the Toxics Chemical Program at the Environmental Defense Fund. She has served on the editorial boards of eight scientific journals and is a member of the Board of Scientific Counselors of the National Institute of Environmental Health Sciences at NIH. She has been a consultant on occupational and environmental health to, among others, the U.S. Secret Service, the Environmental Protection Agency, and the Food and Drug Administration, and has published more than 100 scientific articles.